Appln. S.N. 10/823,475 Amdt. dated May 3, 2010 Reply to Office Action of February 3, 2010 Docket No. 200309746-1 Page 8 of 13

REMARKS

The Office Action of February 3, 2010 has been received and carefully reviewed. It is submitted that, by this Amendment, all bases of rejection are traversed and overcome. Upon entry of this Amendment, claims 18, 19, 21-36, and 38-43 remain in the application. Claims 29-36 have been withdrawn. Reconsideration of the claims is respectfully requested.

Claims 18 and 42 have been amended herein. Support for these revisions may be found throughout the application as filed, at least at page 3, lines 13-21 and page 6, line 25 through page 7, line 9.

Claims 18, 19, 21, 26-28, 38, 42 and 43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Beavis, et al. (U.S. Patent No. 7,146,977) in view of Lloyd, et al. (U.S. Patent No. 5,522,385). The Examiner states that Beavis teaches all of the elements of the Applicants' independent claims 18, 26, 38 and 42, except for at least one selectively disabled resistor and disabling the resistor during a second maintenance mode. The Examiner relies upon Lloyd for this deficiency. In fact, the Examiner states that "...the heating element is implemented only during delivery of the formulation inherently implying that the resister 13/5 is disabled during the non-delivery state..." (see page 4 of the instant Office Action).

Applicants respectfully disagree with the Examiner regarding the heating mechanism of Lloyd. For the reasons set forth herein, the Applicants submit that the combination of the references does not teach or suggest a selectively disabled resistor, and thus does not render obvious the Applicants' invention as defined in the independent claims.

As previously stated, the Examiner admits that Beavis does not teach or suggest a selectively disabled resistor. Contrary to the Examiner's assertion, it is submitted that Lloyd does not supply this deficiency. Lloyd teaches that a heating mechanism is used to add energy to a carrier/particle mixture present in a channel in an amount sufficient to evaporate the carrier and reduce the particle size for delivery of the particles to a patient (see Abstract). Lloyd further teaches that the heating

Appln. S.N. 10/823,475 Amdt. dated May 3, 2010 Reply to Office Action of February 3, 2010 Docket No. 200309746-1 Page 9 of 13

mechanism adds energy to the formulation "prior to or after it is aerosolized" (see Col. 9, lines 47-48), and that "when the formulation 10 enters the cavity 12 it can be heated by means of the formulation heating mechanism 13" or "the formulation can be forced through the pores of the membrane 14 and aerosolized and energy can be added thereafter by means of the air-heating mechanism 5..." (see Col. 10, lines 8-18). In all of the teachings of Lloyd, if the formulation is allowed to flow through the device, the formulation is aerosolized. As such, Lloyd teaches that the heating mechanism(s) are operable every time the device is activated for release of the formulation.

This is not the same type of resistor as the Applicants' selectively disabled resistor. When a resistor is disabled, it is "unable to perform a certain action" (see http://wordnetweb.princeton.edu/perl/webwn). In the Applicants' invention as defined in the pending claims, the resistor is disabled during a maintenance mode. As such, during this mode, the resistor cannot atomize the fluid. The open valve and the disabled resistor of the Applicants' devices as defined in the pending claims enable fluid to be purged from the fluid delivery unit.

Again, Lloyd does not teach that the resistor is ever *disabled* during fluid flow. In fact, as set forth above, Lloyd very specifically teaches that whenever fluid flows through the device, the heating mechanism(s) are activated. The Examiner essentially concludes that during an off state (i.e., a non-delivery state), Lloyd's resistor is inherently disabled. Applicants disagree because an off state is simply a state when the heating mechanisms are not engaged. During such a state, these heating mechanisms are still capable of performing heating, and are activated whenever fluid flows. It is noted that the Applicants' maintenance (or ejector purge) mode is <u>not</u> a non-delivery state. Rather, the second maintenance mode is a state during which any remaining fluid is purged from the device. As such, fluid is flowing in the Applicants' second maintenance mode by virtue of the open valve and the disabled resistor. In view of the teachings of Lloyd, if the fluid is flowing, the heating mechanism is working to evaporate the carrier and provide "repeatability along with

Appln. S.N. 10/823,475 Amdt. dated May 3, 2010 Reply to Office Action of February 3, 2010 Docket No. 200309746-1 Page 10 of 13

automatic control of the drug release mechanism" (see Col. 18, lines 66-67). Since Lloyd teaches aerosolization whenever fluid moves along the flow path, one would not conclude that the resistor is a selectively disabled resistor that can be disabled to allow a fluid purge to take place.

Furthermore, since Lloyd teaches that the heating mechanism(s) are operated when the formulation enters the cavity or after the formulation is forced through the pores of the membrane, one skilled in the art would not be led to disable the heating mechanism(s) even if such mechanisms were included in Beavis's device. Rather, if Beavis's valve were opened, in view of Lloyd's teachings, the heating mechanism(s) would be activated to evaporate carrier and reduce particle size. Again, this is in sharp contrast to the Applicants' devices as defined in the pending claims, because the disabled resistor(s) allow the fluid to purge through the drop ejector, without being atomized.

Since the combination of the references does **not** include a selectively disabled resistor, the Applicants submit that the combination of Beavis and Lloyd does not anticipate or otherwise render obvious the Applicants' invention as defined in the pending claims. For all the reasons stated above, it is submitted that Applicants' invention as defined in independent claims 18, 26, 38 and 42, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

Claims 22-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd, and further in view of Poole (U.S. Patent No. 6,158,431).

The Applicants reiterate the arguments set forth hereinabove and further submit that Poole does not supply the deficiencies of Beavis and Lloyd outlined above. In particular, Poole teaches a piezoelectric driver for oscillating a nozzle. This is in sharp contrast to the Applicants' recited selectively disabled resistor.

Appln. S.N. 10/823,475 Amdt. dated May 3, 2010 Reply to Office Action of February 3, 2010 Docket No. 200309746-1 Page 11 of 13

For all the reasons stated above, it is submitted that Applicants' invention as defined in independent claims 18, 26, 38 and 42, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

Claims 25 and 39-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Beavis in view of Lloyd, and further in view of Koerner, et al. (U.S. Pat. Pub. No. 2004/0195352).

The Applicants reiterate the arguments set forth hereinabove and further submit that Koerner does not supply the deficiencies of Beavis and Lloyd outlined above. Koerner discloses a microdosing device that has both an atomizing unit for delivering a dosing of a liquid quantity of medication and a drying function unit (see Koerner, Figure 1). The drying function unit rids the device of liquid residues left over from dosing by the atomizing unit. The drying function unit operates by piezoelectric vibration, heat, or other means to rid the device of liquid residue. Each possible form of the drying function unit is a separate unit from the atomizing unit. In the embodiments specifically described, the drying function unit is either a piezoelectric actuator or a heater.

At most, the Applicants submit that the combination of the references results in a device including an atomizer (taught in all three references) and a heating mechanism/drying unit (as taught by Lloyd or Koerner).

Applicants' recited ejector head includes a selectively disabled resistor, which is not taught or suggested by the references. Furthermore, the Applicants' maintenance mode is achieved by opening the valve and disabling the at least one resistor. This is in sharp contrast to the teachings of both Lloyd and Koerner. As mentioned above, Lloyd specifically teaches that the heating mechanism(s) are activated during fluid flow. This is the opposite of the Applicants' claims, which includes a **disabled** resistor during fluid purging (i.e., maintenance mode). Furthermore, Koerner specifically utilizes an actuator or a heater to rid the device of

Appln. S.N. 10/823,475 Amdt. dated May 3, 2010 Reply to Office Action of February 3, 2010 Docket No. 200309746-1 Page 12 of 13

residue. As such, when Koerner does include a heater, such heater is activated during cleaning/maintenance. This is the opposite of the Applicants' claims, which includes a **disabled** resistor during maintenance mode. As such, it is submitted that the combination of Beavis, Lloyd and Koerner does not teach or suggest the Applicants' invention as defined in the pending claims.

For all the reasons stated above, it is submitted that Applicants' invention as defined in independent claims 18, 26, 38 and 42, and in those claims depending ultimately therefrom, is not anticipated, taught or rendered obvious by the cited references, either alone or in combination, and patentably defines over the art of record.

If claim 18 is found to contain allowable subject matter, it is requested that the Examiner also consider claims 29-36 for rejoinder. Claims 29-36 are method of using claims which require all of the limitations of the medication delivery device as defined in claim 18. Thus, under the requirements of MPEP §821.04(b), if claim 18 is found to be allowable, it is submitted that claims 29-36 are eligible for rejoinder, and the previous restriction requirement of claims 29-36 should be withdrawn.

It is submitted that the absence of a reply to a specific rejection, issue or comment in the instant Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this amendment should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this amendment, and the amendment of any claim does not signify concession of unpatentability of the claim prior to its amendment.

In summary, claims 18, 19, 21-36, and 38-43 remain in the application. In view of the foregoing arguments, all pending claims are believed to be in condition for allowance, and such action is respectfully requested. Therefore, this response is believed to be a complete response to the Office Action, and further and favorable consideration is respectfully requested.

It is believed that no extensions of time or fees are required, but to the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made.

Appln. S.N. 10/823,475 Amdt. dated May 3, 2010 Reply to Office Action of February 3, 2010 Docket No. 200309746-1 Page 13 of 13

Please charge any shortage in fees due in connection with the filing of this Amendment, including extension of time fees, to Deposit Account 08-2025, and please credit any excess fees to such deposit account.

If the Examiner believes it would expedite prosecution of the above-identified application, the Examiner is cordially invited to contact the undersigned attorney at the below-listed telephone number.

Respectfully submitted,

DIERKER & ASSOCIATES, P.C.

/Julia Church Dierker/

Julia Church Dierker Attorney for Applicants Registration No. 33368 (248) 649-9900, ext. 25 juliad@troypatent.com

3331 West Big Beaver Rd., Suite 109 Troy, Michigan 48084-2813 Dated: May 3, 2010 JCD/JRK/jmo